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Leroy E. Hood

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MCDERMOTT, WILL & EMERY
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SAN DIEGO, CA 92130-2047

EXAMINER

SMITH, CAROLYN L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/993,312	Applicant(s) HOOD ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-77 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 44-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-33,35-43,75-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 11/24/08, has been entered.

Amended claims 1, 16, 32, and 75, filed 11/24/08, are acknowledged. Claims 34 and 44-74 remain withdrawn as being drawn to non-elected subject matter.

Claims 1-2, 4-33, 35-43, and 75-77 are herein under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-33, 35-43, and 75-77 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-2, 4-33, 35-43, and 75-77 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. It is noted that the instant claims 1, 16, 32, and 75-77 recite “identifying correlative changes”; however, this limitation is not a transformation of an article to a different state or thing. It is further noted that claims 1-2, 4-33, 35-43, and 75-77 do not explicitly require that the steps of the claimed method are performed on a machine. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-33, 35-43, and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Rine et al. (P/N 5,777,888).

Rine et al. disclose analyzing stimulus-response patterns of a living thing using deduction protocols applied through artificial intelligence systems such as expert systems and neural networks (abstract, Figure 5) as well as computer protocol to predict myocardial infarction (col. 1, second paragraph) which represents predicting the behavior of a biochemical system, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing comparisons to deduce the mechanism of action and characteristics of the responsible stimulus (col. 5, lines 37-49) which represents a prediction of cell behavior (of a biochemical system) indicative of a changing condition, as stated in claims 1, 16, 32, and 75-77. Rine et al. disclose constructing a stimulated physical matrix (data integration map which is a physical interaction map), detecting a physical signal (value) at each unit of the physical matrix and storing the output signal matrix data with X and Y coordinates of the corresponding physical matrix unit and stimulus (i.e. value sets), and repeating this procedure including constructing a stimulated physical matrix for a plurality of stimuli to form a database (col. 2, lines 4-15) and comparing the output signal matrix to an output signal matrix database (other matrices) which represents producing and comparing two or more data integration maps obtained under different conditions. Rine et al. disclose using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent two or more different perturbed conditions, as stated instant claims 1, 7, 16, 22, 32, 36, and 75-77. The term “network” is broadly defined in several ways in the instant specification (page 10, line 26 to page 11, line 32) that includes a group of interacting molecules in two or more pathways and have common

function in a biochemical function. A “network” is also defined as containing one or more components involved in a biochemical function which could be interpreted to be a cell, nucleic acid, or countless other cellular component parts. Thus, two cells involved in each microarray as discussed by Rine et al. would qualify as two independent networks, as stated in instant claims 1, 2, 16, 17, 32, 33, and 75-77. Rine et al. disclose using a microtiter plate with 96 wells with a cell or colony of cells in each well (col. 10, lines 38-41) which represent at least 96 networks, as stated in instant claims 6, 21, and 35. Rine et al. disclose comparing an output signal matrix to an output signal matrix database (containing other matrices) for correlating candidate stimuli and responses (abstract and col. 1, line 66 to col. 2, line 3 and col. 2, lines 25-29) which represents identifying correlative changes relative to one or more of the value sets between two or more data integration maps and predicting a behavior indicative of a changing condition, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing comparisons to generate correlates and qualitative and/or quantitative deduction analyses (col. 5, lines 56-63 and Figures 5 and 7) which represent producing a comparison of two or more data integration maps and identifying correlative changes in at least two value sets, as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose performing a compound treatment function by contacting each unit of the matrix with a test compound and a reference subtraction function wherein the appropriate reference response profile is subtracted from the response profile, and the difference stored in the knowledge base as the first chemical response profile (alternatively, the response profile is divided by the appropriate reference profile to yield an induction ratio) which is repeated for compounds or mixtures of compounds 2 through N (col. 11, fourth paragraph) as well as detecting changes and outputting correlative results and a user interface (Figures 6 and 7; col. 5,

fourth and fifth paragraphs; col. 3, first paragraph; col. 7, last paragraph; col. 12, third paragraph), as stated in instant claims 1, 16, 32, and 75-77. Rine et al. disclose artificial intelligence systems integrating data accumulation and neural network systems with networks of interconnected processing elements which have multiple input signals and an output signal (col. 1, second and third paragraphs) as well as measuring basal response of each cell under a variety of physical conditions and using an array containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44, col. 11, third paragraph; Figures 6 and 7), all units in a matrix may have the same identifier (col. 3, third paragraph) and a response profile (i.e. value set) incorporating preferably all the responders of the organism to obtain an in vitro or cell culture model, including units reporting gene expression, DNA-protein interaction, and protein-protein interaction (col. 3, last paragraph to col. 4, second paragraph) which represent at least three different types of data elements integrated into value sets (as stated in instant claims 1, 4, 16, 18, 19) and at least five components (as stated in instant claims 14, 29, and 41). Rine et al. disclose measuring gene expression levels in cells (col. 4, lines 11-17) and using various conditions/perturbations, including pharmaceutical agent stimuli, suspected pathogenic agents, and radiative energy (col. 3, lines 48-51) which represent a nucleic acid expression data element type and a physical interaction data element, as stated in instant claims 5, 13, 15, 20, 28, 31, 32, 40, 43, and 75-77. Rine et al. disclose measuring responses for each cell in the matrix under a variety of conditions, such as pH, temperature, medium, and osmolarity

(col. 11, lines 21-28) which represents multiple data elements. Rine et al. disclose measuring cells of the matrix before and after interactions with a pharmacological agent which might include monitoring as a function of other variables such as stimulus intensity, duration, or time (col. 4, lines 51-57) which represents repeated measurements on at least two value sets with three data element types with perturbed conditions for substantially all components within at least one network (as stated in instant claims 8, 23, and 37) as well as obtaining a first integration map and producing a second integration map under a perturbed condition, as stated in instant claims 16, 32, 76, and 77. Values taken during the drug interaction measurements over time as discussed above in a 96-well microtiter plate represent value sets within the same network (measurements in the same well) as well as within different networks (measurements in different wells) as stated in claims 9, 10, 24, and 25. Rine et al. disclose a system for creating physical matrices, storing the matrices in a database, and a comparison function (col. 3, lines 9-19) as well as repeating the process of creating response profiles for compounds 2 through N (any number, i.e. 3) (col. 11, lines 30-40) which represents data integration maps comprising changes in three or more value sets, as stated in instant claims 11, 26, and 38. Rine et al. disclose similarities in a shared response pathway in sterol biosynthesis between human cells and yeast cells resulting increased expression levels but in different nucleic acids when exposed to drug Mevacor (col. 6, lines 14-28). Rine et al. disclose using a microtiter plate to test an inhibitor on various strains of yeast which varies in no expression, increased expression, or decreased expression depending on the strains (col. 6, lines 44-54) which represents inversely coordinated changes in nucleic acid expression data elements, as stated in claims 12, 27, and 39. Rine et al. disclose measuring cells of the matrix before and after interactions (col. 4, lines 51-57) as well as constructing a

stimulated physical matrix, detecting physical signals, storing the data, and iteratively storing signal matrix data for a plurality of stimuli to form a matrix database (col. 2, lines 4-15) which represents repeating steps at least once under a different perturbed condition, as stated in instant claims 30 and 42. Rine et al. disclose comparing a response profile to a reference profile and repeating the process for compounds or mixtures of compounds 2 through N (col. 11, lines 29-40). Rine et al. disclose using this procedure in testing drug administration (perturbation and physical interaction) to identify compounds with a particular biological effect (col. 1, lines 40-57). Rine et al. disclose steps to generate various response profiles (including value sets) for known and unknown stimuli (col. 2, lines 60-64). Rine et al. disclose using a wide variety of stimuli and adjusting incubation conditions to preclude cellular stress (col. 3, lines 59-63). Thus, Rine et al. anticipate the instant invention.

Applicant summarizes the rejection. Applicant argues that Rine et al. fail to disclose the integration of different types of data elements into each value set. This statement is found unpersuasive as “integrate” has been interpreted broadly and reasonably. Rine et al. disclose artificial intelligence systems integrating data accumulation and neural network systems with networks of interconnected processing elements which have multiple input signals and an output signal (col. 1, second and third paragraphs) as well as measuring basal response of each cell under a variety of physical conditions and using an array containing a different responder of a living thing in each unit which may comprise an organism’s entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a

predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44, col. 11, third paragraph; Figures 6 and 7) which represent two or more different types of data elements integrated into each value set. Applicant argues the claimed invention is directed to elements which the cited reference fails to teach. This statement is found unpersuasive as "data element" has been defined very broadly as described in the instant specification (see pages 18-19), and some of the data elements are recited in the cited reference (as described above). Applicant again summarizes the invention and argues that Rine et al. fail to describe an integration of different types of data elements. This has already been found unpersuasive as discussed above. As pointed out by Applicant, "data element" can include nucleic acid expression, protein expression, etc. But it can also include a value or other analytical representation, a number, a symbol, a color, a shape, a set of coordinates, a property of a biochemical system component, etc. as stated on pages 18-19 of the instant specification. Rine et al. disclose measuring basal response of each cell under a variety of physical conditions and using an array containing a different responder of a living thing in each unit which may comprise an organism's entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism's entire repertoire as well as a sufficient ensemble of responders to deduce the action of a stimulus (col. 2, lines 30-44, col. 11, third paragraph; Figures 6 and 7). While the limitation "two or more different types of data elements are integrated into each of said value sets" may encompass a plethora of different scenarios, one example in Rine et al. includes an array with units. As described above, Rine et al. measures a basal response under multiple conditions (conditions are

integrated into a basal response). Also, an array may contain several different element “responders” (i.e. gene transcripts, translates, genes) which are incorporated into the model. This means the data elements are integrated into each value set. Rine et al. provide countless other examples, as described above. Applicant argues that the different responders are separated into different X and Y coordinates and there is no integration of data elements into a data set because the units are separated. This statement is found unpersuasive as “integrated” has been interpreted broadly and reasonably. Rine et al. disclose using an array which may comprise an organism’s entire repertoire of responders including genes, gene regulatory elements, gene transcripts (mRNA) or translates (proteins), or a predetermined functional class or subset of the organism’s entire repertoire as well as a sufficient ensemble of responders (i.e. different types of data elements) to deduce the action of a stimulus (col. 2, lines 30-44), all units in a matrix may have the same identifier (col. 3, third paragraph) and a response profile (i.e. value set) incorporating preferably all the responders of the organism to obtain an in vitro or cell culture model (i.e. value set), including units reporting gene expression, DNA-protein interaction, and protein-protein interaction (col. 3, last paragraph to col. 4, second paragraph). Applicant argues that each identifier in Rine et al. reports on a separate unit. This statement is found unpersuasive as Rine et al. disclose all units in a matrix may have the same identifier (col. 3, third paragraph). Therefore, all values associated with such units are incorporated into a larger unit, i.e. integrated, into the matrix. Applicant further summarizes that stimulus, physical signal, and transformation or storage into an output matrix fails to integrate data elements. It is noted that output of a matrix containing various data elements is incorporating data elements into a larger unit, i.e. integrating into a matrix.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-33, 35-43, and 75-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Thalhammer-Reyero (US 2005/0273305 A1).

Thalhammer-Reyero discloses methods for modeling and simulation of biochemical networks of pathways, including metabolic, signal transduction and regulatory pathways within a cell or across cells, determining the effect that modulating one or more reactions in a biochemical pathway has on an operation of the biochemical pathway, and for simulating or predicting an altered physiological state of cells (abstract) as stated in the preamble of instant claims 1, 16, 32, and 75-77. Thalhammer-Reyero discloses a method of predicting a behavior of a biochemical system, comprising obtaining a first integration map of a biochemical system comprising value sets of two or more integrated data elements for at least one network, producing a second data integration map of said biochemical system under a perturbed condition, said second data integration map comprising perturbed value sets of two or more integrated data elements for said at least one network, comparing and identifying correlative changes in at least

two value sets relative to one or more value sets in the data integration map with said perturbed condition, wherein said correlative changes predict a behavior of said biochemical system as well as an integrated framework and an integration of a variety of forms of knowledge representation (0003, 0006, 0014-0018, 0020, 0023-0024, 0039, 0081, 0093-0094, 0154, 0159, 0184, 0281-0282, 0369, 0453-0455, 0563-0564, claims 259 and 142, Figure 1) as stated in instant claims 1, 9, 10, 16, 32, 24, 25, and 75-77. Thalhammer-Reyero discloses modeling disease specific conditions and comparing against each other or specified values (0028, 0084), as stated in instant claims Thalhammer-Reyero discloses providing output (0036, 0097, 0140). Thalhammer-Reyero discloses a biochemical system is selected from the group consisting of a cell, tissue and organism, or a constituent system thereof (claim 260), as stated in instant claims 2, 17, and 33. Thalhammer-Reyero discloses three or more data elements (claim 413), as stated in instant claims 4, 11, 18, 19, 26, and 38. Thalhammer-Reyero discloses data elements corresponding to physical interactions (0017), as stated in instant claims 5, 20. Thalhammer-Reyero discloses three or more networks (claim 412), as stated in instant claims 6, 21, and 35. Thalhammer-Reyero discloses two or more perturbed conditions (claim 261), as stated in instant claims 7, 8, 22, 23, 36, and 37. Thalhammer-Reyero discloses inverse changes (0434, 0514), as stated in instant claims 12, 27, and 39. Thalhammer-Reyero discloses correlative changes in at least two value sets within said second data integration map further comprise value sets selected from the group consisting of protein expression, polypeptide-polypeptide interaction, nucleic acid-polypeptide interaction, metabolite abundance, and growth rate (claim 414), as stated in instant claims 13, 28, and 40. Figure 2 shows at least five components, as stated in instant claims 14, 29, and 41. Thalhammer-Reyero discloses allowing repeated use of entities as building blocks in

a variety of situations (0094, 0141, 0576), as stated in instant claims 30 and 42 Thalhammer-Reyero discloses behavior is selected from the group consisting of cellular phenotype, biochemical activity, expression level and accumulation level (claim 262), as stated in instant claims 15, 31, and 43.

Thus, Thalhammer-Reyero anticipates the instant invention.

Applicant summarizes the rejection. Applicant summarizes Thalhammer-Reyero paragraphs 0003, 0006, 0014-0017, 0020, 0093, 0453, claims 142 and 259 and argues that the “integration of a variety of forms of knowledge representation[s]” in Thalhammer-Reyero is distinct from the claimed invention because there is no teaching of integrating at least two different types of data elements into each value set. This statement is found unpersuasive as Thalhammer-Reyero discloses integration of building blocks and access panels, that allow for representation, interpretation, and modeling and simulation of different types of entities and their states, their relations and interactions (0017), integration of input units and linking of values of encapsulated sets of variables (0020), integrating components of a model into networks of interacting pathways (0024), integration of measured values (0039), integrating variables with other variables and parameters (0081), integrating qualitative and quantitative description of chemical and biochemical objects with a set of state and dependent variables, such as amounts and rates (0094), integrating temperature and pH into the simulation within the appropriate equations (0154), values of attributes from different sources are integrated (0184), integrating and modeling bioentities (0368-0369), and integration of variables (0564). Applicant argues that the Examiner's statement that claim 259 is found in the originally filed specification lacks

support and is conclusory. This statement is found unpersuasive as support can be found, for example, in Thalhammer-Reyero paragraphs 0016, 0070, 0021, 0082, 0102, 0149, 0589, and Figures, such as, 36a and b. Applicant argues that Thalhammer-Reyero only refers to the integration of knowledge representations. This statement is found unpersuasive as integrating is described throughout Thalhammer-Reyero as already described above. Applicant argues that "data integration map" or "integration map" are absent in Thalhammer-Reyero and she fails to describe a map. This statement is found unpersuasive as Thalhammer-Reyero describe mapping (0082) and a model viewed as a set of block diagrams (0021), a network linking bioObjects, a visual interface displaying modular components of the visual models and the information they contain (0022-0024) and provide integrated map examples, such as, Figures 36a and b. Applicant reiterates arguments that have already been found unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

February 9, 2009

/Carolyn Smith/
Primary Examiner
AU 1631